# Methodological Challenges in Treatment Outcome Research With Ethnic Minorities

Anna S. Lau University of California, Los Angeles Doris F. Chang New School for Social Research

Sumie Okazaki New York University

Treatment outcome research focused on ethnic minorities is critically needed to eliminate mental health disparities. Because the conduct of treatment outcome research with ethnic minorities is difficult and complex, we discuss key challenges and present some methodological options suited to provide answers to specific types of questions. We focus first on the randomized clinical trial (RCT) paradigm, reviewing specific challenges facing investigators conducting ethnically inclusive trials. We then highlight the promise of other methods of inquiry to expand the science on mental health treatment with ethnic minorities.

Keywords: ethnic minorities, treatment outcomes, randomized controlled trials

"What psychological treatment works for whom under what circumstances?" Answering this question is an urgent priority in the context of mental health disparities and high levels of unmet need in underserved ethnic minority communities. In 1994, the National Institutes of Health (NIH) mandated sufficient inclusion of ethnic minorities in all funded Phase III trials to allow valid analyses of ethnic differences in intervention effects (Hohmann & Parron, 1996). Yet 15 years after these guidelines were instituted, attention to issues of racial/ethnic diversity in treatment outcomes remains the exception rather than the rule. Among 379 National Institute for Mental Health (NIMH)-funded trials published between 1995 and 2004 in five major journals, fewer than half even reported the race/ethnicity of the participants, and among those reporting race/ethnicity all minority groups but African Americans were underrepresented (Mak, Law, Alvidrez, & Pérez-Stable, 2007). Thus, the diversification of the evidence base upon which to make treatment decisions remains an aspirational goal.

In this paper we review methodological challenges inherent in treatment outcome research with ethnic minorities. First, because the randomized controlled trial (RCT) represents the field's most widely accepted strategy for examining treatment effects (Concato,

Anna S. Lau, Department of Psychology, University of California, Los Angeles; Doris F. Chang, Department of Psychology, New School for Social Research; Sumie Okazaki, Department of Applied Psychology, New York University.

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Correspondence concerning this article should be addressed to Anna S. Lau, UCLA Department of Psychology, 1285 Franz Hall, Box 951563, Los Angeles, CA 90095-1563. E-mail: alau@psych.ucla.edu

Shaw, & Horwitz, 2000) we discuss challenges in the design and conduct of RCTs with ethnic minorities. Conducting RCTs with ethnic minority groups presents some vexing complications that, in some contexts, render this design untenable or prohibitively costly. Thus, we also review alternatives to the RCT that can also answer important questions regarding the implementation and optimization of mental health treatment for ethnic minorities.

# Methodological Issues in RCTs With Ethnic Minorities

#### **Inclusion of Ethnic Minorities in RCTs**

The NIH requirement for inclusion of ethnic minorities was intended to address the longstanding concern about overgeneralization of RCT findings to ethnic populations heretofore excluded from trials. Ethnically inclusive trials require specialized planning for sampling and engagement. For sites where certain ethnic groups are also numerical minorities, minorities may need to be oversampled relative to non-Hispanic White (NHW) participants with specialized outreach and recruitment. This complicates recruitment, already a difficult challenge for disorders with low population base rates, and any such group difference in methodology presents an alternative explanation for observed ethnic differences in outcomes, thus differences must be anticipated and avoided if possible.

Even when investigators are successful in recruiting diverse samples in RCTs, such inclusion has typically resulted in samples insufficient for meaningful analyses (Mak et al., 2007; Miranda, Nakamura & Bernal, 2003). Subgroup analyses wherein treatment effects are tested separately by ethnicity are criticized because of problems with multiple tests and inflated Type I error. Moreover, such analyses cannot address the question of differential efficacy because they do not examine whether effect sizes differ from each other (Kraemer, Frank, & Kupfer, 2006). Unless inclusive trials are designed a

priori to test ethnicity by treatment interactions (with matching, blocking, or stratification by ethnicity; Chambless et al., 1996), trials are underpowered to determine whether there is invariance or disparity in treatment response among ethnic groups (Huey & Polo, 2008). Without these design features even the largest of multisite trials are severely restricted in their inquiry.

As an illustrative example, the NIMH Multimodal Treatment Study of ADHD (MTA) was conducted by 6 independent research teams who randomized 579 children (including 352 NHW, 115 African American, 49 Latino, and 63 children from other ethnic groups) to receive either usual care, medication management, behavioral treatment, or combination therapy. Post hoc analyses explored ethnic differences in outcome. Using a matched pairs approach, 92 African American and 37 Latino participants were matched to NHW controls on sex, treatment condition, and site. Arnold et al. (2003) reported effect sizes associated with matched pair differences in outcomes and tested ethnicity by treatment interactions with planned contrasts of treatment conditions (e.g., the advantage of behavioral treatment over usual care was greater for Caucasians than African Americans). They emphasized effect sizes and did not adjust for multiple testing, arguing that the probability of a Type II error was already high because of small cell sizes. This case illustrates the limitations of even the largest of ethnically inclusive trials that are still insufficient to provide definitive answers about ethnic variation in treatment response. Questions remain: Should we attend to differential effects based on small samples? What can we infer from the absence of significant ethnicity by treatment interactions given insufficient power to detect moderation?

Another issue exemplified in the MTA study is that selecting participants representative of ethnic communities may produce comparison samples that differ on key dimensions (e.g., diagnostic severity, SES). Arnold et al. (2003) reported that both of the ethnicity by treatment interactions were rendered nonsignificant when SES was covaried. Such a finding is often taken as evidence that ethnicity is unimportant or that ethnic differences in treatment response are fully accounted for by the effects of socioeconomic disadvantage, but this is a strong inference. SES is confounded with minority status in the United States, and to attribute the variance in effects to one variable in a two-variable confound is a problematic supposition (Miller & Chapman, 2001).

Beyond pragmatics and methodological constraints, scholars question the rationale and wisdom of conducting inclusive multiethnic RCTs designed to test ethnicity as a moderator. Such comparative approaches may not be motivated by theoretically guided hypotheses and may promote a deficit view of ethnic minorities when disparities are found (Yali & Revenson, 2004). In contrast, trials focused on specific ethnic groups can permit examination of treatment response as a function of culturally relevant variables (e.g., acculturation) thereby advancing theory and providing guidance in the selection of treatments based on a more refined set of patient characteristics (Bernal & Scharron-Del-Rio, 2001; Hall, 2001).

# **Examining Within-Group Heterogeneity** in Treatment Response

Given the enormous challenges involved in recruiting and retaining ethnic minorities in RCTs, researchers must weigh the need for a sizable sample that retains homogeneity on relevant clinical dimensions (e.g., diagnosis) against the impetus to purposively sample for within-group differences on sociocultural factors (e.g., SES, acculturation and enculturation, religion, language, etc.) that may moderate efficacy. Moreover, each ethnic community has its own set of vectors of diversity that complicate sampling. For example, there are 561 federally recognized Native American tribes and over 200 indigenous languages spoken, with vast cultural differences in customs, family structures, religions, and community contexts (U.S. Department of Health and Human Services [U.S.D.H.H.S.], 2001). The majority of Asian Americans and Latinos are first generation immigrants or refugees, but a sizable minority in each community trace their roots back multiple generations in the United States. Among Latinos, for example, the prevalence of mental illness varies not just by nativity but also by national origin (Alegría et al., 2008).

Sampling design for RCTs with ethnic minorities could be based on theoretically driven hypotheses about the interaction of the particular ethnic group's sociocultural position with specific elements of the treatment. For example, La Roche et al. (2006) illustrated how a theoretically important cultural orientation can predict within-group differences in response to a culturally adapted evidence-based treatment. In an open trial with Latino adults, they evaluated Culturally Competent Relaxation Intervention (CCRI) designed to be consistent with allocentric values of interdependence, employing guided imagery exercises emphasizing interpersonal connection as opposed to more canonical solitary, peaceful imagery. Participants who strongly endorsed allocentric values showed higher treatment adherence, which was linked in turn to greater reductions in anxiety. A more conclusive design might have stratified patients on levels of allocentrism and randomized them to CCRI versus a more solitary guided imagery protocol.

#### Language Inclusion

Decisions regarding inclusionary and exclusionary criteria based on language pose particular challenges in clinical trials research with ethnic minorities. For example, 55% of Latino American adults have limited English proficiency (Suarez-Morales et al., 2007). Nearly 40% of Asian Americans speak a language other than English at home and speak English "less than very well," but this rate ranges from 23% among Asian Indians to 62% among Vietnamese (Reeves & Bennett, 2004). Research suggests that the language used with bilingual patients may affect clinicianrendered diagnostic assessments (e.g., Malgady & Constantino, 1998), and providing psychotherapy to non-native English speakers in English is associated with smaller treatment effects (Griner & Smith, 2006). It is imperative that trials provide assessment and treatment in the appropriate language(s) and dialect(s) spoken by the ethnic group under study. However, a meta-analytic review of 76 studies evaluating interventions culturally adapted for ethnic minorities revealed that 40% of the studies included only native English speakers (Griner & Smith, 2006). Of those trials including non-native English speakers, 25% provided treatment only in English. These numbers reflect the sheer difficulty of conducting RCT studies with non-native English speakers.

For RCTs with minority participants who are not native English speakers, recruitment and retention of each cultural-linguistic group may require its own bilingual-bicultural research and treat-

ment team. The limited availability of instruments that have already been translated and validated in the desired language complicates the methodology considerably. Moreover, careful translation and back-translation of measures and study-related materials is necessary but not sufficient for achieving linguistic competence. For a discussion of the complexities of assuring linguistic, conceptual and cultural equivalence in translation see Matías-Carrelo et al. (2003). Further, variation in national origin and regional differences in language necessitate a careful review of translated materials to ensure their appropriateness for ethnic subgroups who share the same primary language (Suarez-Morales et al., 2007). In sites with shortage of language-matched clinicians, interpreters may be used. However, interpretation in psychotherapy is an arduous undertaking and should follow systematic protocols to assure that care is delivered ethically, with fidelity, and with interpreters educated in psychopathology and intervention terminology and a working knowledge of the treatment model (d'Ardenne, Farmer, Ruaro & Priebe, 2007).

Even when guidelines for rigorous translation have been followed, there are many reasons why resultant versions may not be comparable to the original. A particular instrument may appear equally reliable in two populations yet cultural differences in the meaning and operationalization of the construct may result in misleading comparisons (Crockett, Randall, Shen, Russell, & Driscoll, 2005). Tests of measurement equivalence establish whether a measure is similarly reliable and valid across different ethnic/language groups (Knight & Hill, 1998). Factorial invariance and construct validity equivalence are important to establishing the comparability of observed score differences across groups. Confirmatory factor analysis provides a method for evaluating hypothesized factor structures and scale/item invariance across groups. Construct validity equivalence, on the other hand, is demonstrated by similarities in the intercepts and slopes of the latent constructs on related constructs across groups. Within the framework of item response theory (IRT), item and scalar equivalence can be examined to identify possible differential item functioning between groups in the relations between observed item responses and the underlying construct.

In trials focused on specific ethnic groups, evaluation of instruments can rest on more conventional psychometric evidence of reliability and validity of the outcome instruments. However, in inclusive multiethnic trials designed to examine questions of possible differential efficacy, considerations of measurement equivalence become paramount, adding markedly to the burden of investigators.

#### **Clinical Samples**

In any trial, well-defined inclusion criteria are necessary to address the research question and determine to which population the study results will generalize. Because population-based sampling of individuals with a given disorder is untenable, RCT samples are routinely recruited from treatment-seekers in mental health settings. However, many ethnic minorities in need lack access to or fail to seek mental health care (U.S.D.H.H.S, 2001). Asian Americans with diagnosable mental disorders are far less likely to receive mental health services as compared to other ethnic groups with the same diagnoses, with disparities more pronounced among immigrants (Le Meyer, Zane, Cho, & Takeuchi, 2009). In

Native American communities, some view mental health services from a postcolonial perspective, equating conventional Western mental health with being "brainwashed . . . so [Indians] can become like Whitemen" (Gone & Alcántara, 2007, p. 361). Consequently, RCTs with ethnic minority participants that sample beyond conventional mental health settings may yield more generalizable findings. Successful investigators have partnered with primary care, corrections, schools, faith-based organizations, and other community agencies to reach ethnic minorities with specific mental health needs. For example, efficacy of CBT for depression in primary care can be increased for low-income Spanish speaking patients through the addition of enhanced case management (Miranda et al., 2003). Diversion into Multisystemic Therapy after multiple arrests and detentions in the juvenile justice system demonstrates that this intervention is effective in reducing recidivism among African American young offenders (e.g., Borduin et al., 1995). Collaboration between educators and clinical researchers has shown that school-based trauma-focused CBT can reduce symptoms among Latino immigrant youth exposed to community violence (Kataoka et al., 2003). Efforts such as these illustrate the potential of implementing interventions outside the mental health sector to engage underserved minorities in RCTs.

#### **Random Assignment**

Randomization in RCTs is the hallmark feature that confers internal validity and permits causal inference about whether a treatment has an effect. However, random assignment to treatment conditions may not appear random for some ethnic minorities who mistrust researchers owing to their community's history of being subjected to exploitative or abusive medical research (Alvidrez & Areán, 2002; Thomas & Quinn, 1991). Some participants may believe that assignment to certain conditions is based on evaluations of their prognosis or other factors. Individuals assigned into a "no treatment" condition may demand inclusion in the treatment group. Corrigan and Salzer (2003) have argued that random assignment can raise unanticipated threats to internal validity, as in the case when participants have clear treatment preferences. Treatment preference among participants affects their likelihood of entering an RCT, engaging in the assigned condition, and completing the treatment. If treatment preference is suspected to be a salient factor within a particular ethnic minority community (Givens, Houston, Van Voorhees, Ford, & Cooper, 2007), it is advisable to pilot test assumptions about randomization and to include an assessment of treatment preference as an independent variable in the study.

Alvidrez and Areán (2002) suggested that increased education about the randomization process, as well as the use of procedures that reduce the perception of assignment being predetermined, may be helpful in allaying ethnic minority participants' skepticism and mistrust. In a clinical trial of antidepressant medication for low-income immigrant Asian Americans in a primary care clinic, Chen, Kramer, Chen, & Chung (2005) found that explaining exactly what would happen (e.g., "after you are assessed you will have an equal chance of getting either of the following treatments...") was understandable and acceptable to prospective participants.

#### **Selection of Comparison Conditions**

Within the RCT tradition, there are several types of comparison groups to which the target intervention can be compared. The simplest design compares the treatment of interest to a notreatment control, permitting examination of whether the intervention is better than the passage of time but not addressing whether, and how, change in the treatment group resulted from specific components of the intervention. A no-treatment control is justified in the absence of evidence that the intervention is more effective than no intervention. A related design involves comparing the intervention to an attention control condition, in which the effects of nonspecific factors such as therapist attention and support can be compared to the effects of the putative "active ingredients" of the intervention. These comparison conditions may not be defensible in tests of the efficacy of EBTs with previously unstudied ethnic minority groups because EBTs by definition have been shown to be efficacious for mainstream samples (Eap & Hall, 2007). As such, it may be unethical to withhold treatment from the control group, and the use of a wait-list may be preferred as a control. Delayed treatment controls for spontaneous remission that can occur with time and allows for the assessment of the effects of hope and expectancy associated with the knowledge that treatment is forthcoming. However, some ethnic communities may have dense social networks such that waitlisted participants may inadvertently receive information from their contacts regarding the intervention (Eap & Hall, 2007). Strategies for countering the threat of diffusion include the use of multiple baseline interrupted time series design, with small comparable communities receiving the intervention in sequence.

Other trials compare the relative efficacy of two or more "active" treatments, with the goal of demonstrating superiority of one intervention or equivalence to a "gold standard" intervention. A growing body of literature has examined the efficacy of culturally adapted versions of EBTs (for review see Griner & Smith, 2006). Some investigators have used no treatment or wait-list controlled designs to demonstrate that culturally adapted EBTs are efficacious and robust to modifications when applied to ethnic minority samples (e.g., Hinton et al., 2005; Martinez & Eddy, 2005). Other investigators have compared culturally adapted EBTs to their standard EBT counterpart to examine any "incremental value" of cultural modifications (e.g., Huey & Pan, 2006; McCabe & Yeh, 2009). Posing questions of relative efficacy necessitate larger trials with greater power to be able to detect what could only be expected to be smaller effect sizes given that the two conditions contain potent treatments. Indeed, holding culturally adapted interventions to a standard of demonstrating superiority over wellresearched EBTs can place an additional burden on intervention researchers focused on ethnic minority populations.

In cases where the main question concerns the external validity of the intervention (i.e., is the intervention more effective when applied to the general population than what currently exists?) the comparison condition is treatment as usual (TAU). A TAU control consists of the routine intervention(s) ordinarily provided by clinicians in the settings from which participants are recruited (Mohr et al., 2009). RCT's with TAU comparison groups address the question, 'Would adopting this treatment, in lieu of routine care, significantly improve outcomes in this setting?' Thus, trials with TAU comparisons may have the potential for encouraging the

uptake of EBTs in real world practice contexts. However, TAU in some community settings for ethnic minorities may be no treatment or substandard treatment due to multiple barriers that prevent access to even minimally effective care (e.g., lack of languagematched providers; Alvidrez & Areán. 2002). Access to minimally effective treatment may also vary according to level of acculturation such that monolingual, recent immigrants may be least likely to have access (Eap & Hall, 2007). Thus, comparison to TAU raises ethical issues concerning the reality of limited access to any treatment in underserved communities. For some disorders such as depression where a clear minimal standard of care exists, nonconforming TAU may be unethical (Alvidrez & Areán, 2002). In such cases, researchers must evaluate carefully the aims of the research and the outcomes under examination. If the study is focused on increasing utilization and access for a minority community, TAU may be an appropriate comparison. However, if the study is examining the efficacy of a specific treatment, then TAU should include some assurance of access to guideline concordant care.

#### **Assessment of Outcomes**

It is an accepted principle to use multiple methods of outcome assessment to avoid the limitation bias of any one method. Measures—whether they are interviews, self-report, or behavioral assessment—must be precise, sensitive to change, and validated for the sample (e.g., age, language, ethnicity). Much has already been written about culturally appropriate clinical assessment with ethnic minorities (e.g., Okazaki & Tanaka-Matsumi, 2006). One issue worth highlighting is the consideration of multiple dimensions of outcome that are relevant to clients and their families, practitioners, researchers, and other stakeholders (such as policymakers, third party payers). Mendenhall (2008) argued that unless the consumers are actively involved in understanding and naming their own outcomes, assessments may be perceived as yet another instance of professionals imposing their own abstract definitions of wellness and illness. Such risk might be especially heightened for members of ethnic communities who are particularly vulnerable due to lack of economic, political or social capital. Qualitative research on symptom expression and functioning within ethnic communities may help determine culturally meaningful outcome indices (e.g., Hinton & Otto, 2006). Researchers also cannot assume that interventions will have equivalent effects on symptoms and functional impairment outcomes across ethnic groups. For example, the impairment associated with depression symptoms appears to differ between Latinos and Whites (Huang, Chung, Kroenke, & Spitzer, 2006) and less improvement in impairment has been observed in African Americans receiving CBT compared to other groups (Miranda et al., 2003). A combined quantitative and qualitative approach may help identify the relevant dimensions of symptoms and impairment that are meaningful to ethnic minorities in clinical trials.

# Beyond the RCT

By incorporating theoretically driven questions about treatment response among ethnic minorities into experimental designs, RCTs can transcend basic questions of efficacy and relative efficacy to generate answers about the mechanisms of action in psychotherapy for ethnic minorities. However, the technical complexity, execution time, and costs of RCTs increase greatly when minorities comprise the target group. Even after efficacy is demonstrated, questions remain regarding how well treatment effects will transfer into real-world settings when experimental controls are lifted. Given the urgent need to improve care for ethnic minorities, we are heartened by the proliferation of innovative research strategies that have emerged to address these and other limitations of RCTs. Below, we discuss alternative research strategies and highlight their potential to rapidly identify, test, and deliver effective treatments to underserved communities.

# **Alternatives to Group Designs**

One only has to enter a community mental health clinic in any major city in the United States to witness the tremendous diversity that characterizes the patient population. In a perfect world, treatment decisions at the idiographic level would be guided by evidence of a treatment's effectiveness for the particular problem in individuals similar to the patient on several dimensions. However, the evidence base will likely never yield efficacy data for specific groups for specific treatments. And when dealing with small but high-risk patient populations (e.g., Somali refugees with complex PTSD), there is a need for cost-effective research designs that can quickly identify promising interventions for further exploration.

Single treatment open trials (STTs) and single case design experiments (SCDEs) offer the ability to make causal inferences about treatment effects while requiring fewer resources than RCTs. STTs differ from RCTs in a number of ways, the most important of which are that a) sample sizes tend to be modest, b) there is no comparison group, and c) researcher and patient are aware of the treatment that is being evaluated. As a result, such trials are subject to experimenter bias and the placebo effect. Nevertheless, they have been conducted with increasing frequency to obtain preliminary evidence of efficacy, determine the feasibility and acceptability of a given treatment for specific patient groups, and ensure that treatments can be administered with fidelity (Crits-Christoph, Connolly, Azarian, Crits-Cristoph, & Shappell, 1996) prior to investing in a costly RCT. STTs may be a useful first step in illuminating hypotheses about cultural factors in engagement and treatment process. Conventional reasoning suggests that without random assignment, any evidence of efficacy must be interpreted with caution and explored further under controlled conditions. Yet, meta-analyses suggest that well-designed SSTs do not systematically overestimate the magnitude of treatment effects compared to RCTs (Concato et al., 2000).

Compared to group designs and the STTs, SCDEs are efficient in their ability to experimentally demonstrate treatment efficacy with a limited number of subjects. In SCDEs (which, despite their name, involve aggregating findings across multiple subjects), participants serve as their own experimental controls and comparisons are made across experimental conditions rather than across comparison groups. A well-specified and extended baseline assessment (analogous to a no-treatment control condition) is a central feature. Repeated objective or subjective assessments of the target problem are made to determine the temporal and/or causal effects of exposure to various intervention conditions.

Yet, SCDEs have had relatively circumscribed impact on the identification of EBTs, limited to interventions from the applied behavior analysis tradition. They are less applicable to treatments

that provide skills training or generate insight that cannot be withdrawn (plausibly) or reversed (ethically). Nonetheless, because single-participant designs are more easily conducted in applied settings than are RCTs due to modest sample requirements and appeal to clinicians, they could play a critical role in the evaluation of EBTs for ethnic minorities. SCDEs may be conducted in ethnic-specific clinics where EBTs may be systematically evaluated for their generalizability. Adopting an idiographic approach allows qualitative exploration of individual differences and the generation of hypotheses regarding the contributions of culture or ethnicity. However, barriers to conducting SCDEs in practice settings include the onerous requirements for repeated assessments including a prolonged baseline assessment (required to demonstrate the problem does not resolve over time without treatment). Another shortcoming of SCDEs is that their findings cannot be generalized beyond individuals who are culturally and clinically similar to subjects. Nevertheless, SCDEs may be a route to examine the generalizability of EBTs already evaluated in noninclusive RCTs.

### Research-Practice-Community Collaborations

A major critique leveled against the use of RCTs as the gold standard for validating treatments for ethnic minorities involves their relevance to the exigencies of "real-world" clinical practice and the broader socioecological context of service delivery. Ethnic minorities have less access to mental health care and the care they do receive is less likely to reflect current best-practices (U.S.D.H.H.S., 2001). Researchers have highlighted the relative ineffectiveness of EBTs when delivered in community practice settings (Weisz, Donenberg, Han, & Weiss, 1995). Others have questioned the clinical utility of research findings removed from the complex realities of the usual care environment (Garland, Plemmons, & Koontz, 2006). Additional criticisms have focused on the inattention to the cultural negotiations that characterize treatment with ethnic minority patients (Ito & Maramba, 2002) and the privileging of treatment techniques over the therapeutic relationship (Strupp & Anderson, 1997).

Recognizing the necessity of bridging these concerns and pooling the collective wisdom of scientists and practitioners, systematic attempts to integrate experimentally and clinically derived knowledge through research-practice-community partnerships have appeared in the literature. Whereas efficacy and effectiveness research are hypothesis-driven, community-based participatory research (CBPR) adopts a discovery-oriented approach (Bernal & Scharrón-Del Río, 2001). CBPR involves collaboration between multiple stakeholders to identify community problems and resources, set research agendas, develop measurement tools, implement study results, and build capacity to for sustaining change (Israel, Eng, Schultz, Parker, & Satcher, 2005). Influenced by principles of action research, CBPR seeks to critically examine dynamics of power and privilege in the research partnership, give voice to individuals' lived experiences, dismantle traditional hierarchies of knowledge, and promote community ownership of the research endeavor (Wallerstein & Duran, 2006). In CBPR the development, packaging, and delivery of interventions are grounded in local illness meanings, explanatory frameworks, and community insights into the problem. Consistent with a discovery focus, CBPR typically makes use of qualitative methods, including ethnography, used solely or in conjunction with quantitative methods (Hohmann & Shear, 2002). In one CBPR study, trauma within Native American communities was adopted as an etiological theory to explain psychological, bodily, and psychosocial problems (Braveheart-Jordan & DeBruyn, 1998 as cited in Wallerstein & Duran, 2006). Healing was thus conceptualized as a communal process, facilitated by public healing rituals to address historical traumas.

Evaluation of CBPR approaches provides evidence of greater community acceptance and participation in interventions that emerge from this collaborative process (Chen et al., 2005). However, establishing causal linkages between the interventions, participation in the research process itself, and health outcomes is hindered by the lack of experimental controls. CBPR may be most influential as a strategy for identifying cultural and structural barriers to care, capitalizing on local resources and indigenous coping frameworks, and empowering underserved populations to collaborate with researchers in developing and delivering sustainable interventions that are consistent with community priorities and values.

Another group of strategies for closing the research-practice gap involves creative fusions of mental health services research, intervention research, and community participatory approaches aimed at the development of sustainable, evidence-based intervention models. Garland, Hurlburt, & Hawley's (2006) "hybrid" model of practice-based research combines the aims and methods of services and interventions research to balance scientific rigor with clinical relevance. Their observational study of community treatment of ethnically diverse children with disruptive disorders combines the service research focus on naturalistic settings with broad inclusion criteria, and aspects of efficacy research with detailed observations of therapy process and analyses linking process to outcomes. This research can generate practice-based evidence relevant to the question of whether mechanisms of change in EBTs generalize across ethnic minority groups.

Other models of research-practice collaboration illustrate different ways of negotiating research, practice, and community agendas. Wells, Miranda, Bruce, Alegria, & Wallerstein (2004) propose an integrated evidence-based community partnership model that involves community stakeholders and practitioners in negotiating health services priorities that are then connected with EBT strategies tailored to the target community. Although varying in terms of their core epistemological assumptions, research goals and designs, power-sharing between partners, and degree of community participation, these approaches signal a positive trend toward the coconstruction of the evidence base. Recognizing multiple subjectivities is especially critical for empowering groups previously underrepresented in research and highlighting aspects of EBTs that are incompatible with the needs of minority populations.

# **Concluding Remarks**

Stemming the progress of research on treatment outcomes for ethnic minorities are numerous operational and methodological burdens encountered by researchers conducting inclusive controlled trials. A range of studies are still sorely needed along the continuum from exploratory open trials and discovery-oriented clinical research, to SCDEs, to tightly controlled efficacy trials, and Phase III effectiveness trials. Within each framework a range

of scientific, methodological, ethical, and logistic decision points represent trade-offs between internal versus external validity, tightly controlled versus real-world practice conditions, and theory-building versus hypothesis testing. The weight of these methodological complexities increases exponentially in trials with multiple cultural, ethnic or language groups. Controlled trials with focal ethnic group target samples may simplify some of these concerns (e.g., burdens of demonstrating measurement equivalence to NHW samples) at the cost of decreasing the range of inferences about treatment generalizability. Methodological approaches beyond the venerated RCT provide opportunities to examine a wide range of questions pertaining to treatment response among less populous ethnic minority groups within both hypothesis-testing and discovery-oriented paradigms. When tackling these obstacles, researchers should take heart in the opportunity to do pioneering work with strong potential for immediate public health impact.

#### References

- Alegría, M., Canino, G., Shrout, P., Woo, M., Duan, N., Vila, D., ... Meng, X.-L. (2008). Prevalence of mental illness in immigrant and non-immigrant U.S. Latino groups. *American Journal of Psychiatry*, 165, 359–369.
- Alvidrez, J., & Areán, P. A. (2002). Psychosocial treatment research with ethnic minority populations: Ethical considerations in conducting clinical trials. *Ethics & Behavior*, 12, 103–116.
- Arnold, L. E., Elliott, M., Sachs, L., Bird, H., Kraemer, H. C., Wells, K. C., . . . Wigal, T. (2003). Effects of ethnicity on treatment attendance, stimulant response/dose, and 14-month outcome in ADHD. *Journal of Consulting and Clinical Psychology*, 71, 713–727.
- Bernal, G., & Scharron-Del-Rio, M. R. (2001). Are empirically supported treatments valid for ethnic minorities? Toward an alternative approach for treatment research. *Cultural Diversity & Ethnic Minority Psychol*osy 7, 328–342
- Borduin, C. M., Mann, B. J., Cone, L. T., Henggeler, S. W., Fucci, B. R., Blaske, D. M., & Williams, R. A. (1995). Multisystemic treatment of serious juvenile offenders: Long-term prevention of criminality and violence. *Journal of Consulting and Clinical Psychology*, 63, 569–578.
- Braveheart-Jordan, M., & DeBruyn, L. (1995). So she may walk in balance: Integrating the impact of historical trauma in the treatment of Native American Indian women. New York: Haworth Press.
- Chambless, D. L., Sanderson, W. C., Shoham, V., Bennett Johnson, S., Pope, K. S., Crits-Christoph, P., . . . McCurry, S. (1996). An update on empirically validated therapies. *Clinical Psychologist*, 29, 5–18.
- Chen, H., Kramer, E. J., Chen, T., & Chung, H. (2005). Engaging Asian Americans for mental health research: Challenges and solutions. *Journal of Immigrant Health*, 7, 109–116.
- Concato, J., Shah, N., & Horwitz, R. I. (2000). Randomized, controlled trials, observational studies, and the hierarchy of research designs. *New England Journal of Medicine*, 342, 1887–1892.
- Corrigan, P. W., & Salzer, M. S. (2003). The conflict between random assignment and treatment preference: Implications for internal validity. *Evaluation and Program Planning*, 26, 109–121.
- Crits-Christoph, P., Connolly, M. B., Azarian, K., Crits-Cristoph, K., & Shappell, S. (1996). An open trial of brief supportive-expressive psychotherapy in the treatment of generalized anxiety disorder. *Psychother*apy: Theory, Research, Practice, Training, 33, 418–430.
- Crockett, L. J., Randall, B. A., Shen, Y.-L., Russell, S. T., & Driscoll, A. K. (2005). Measurement equivalence of the Center for Epidemiological Studies Depression Scale for Latino and Anglo adolescents: A national study. *Journal of Consulting and Clinical Psychology*, 73, 47–58.
- d'Ardenne, P, Farmer, E., Ruaro, L., & Priebe, S. (2007). Not lost in

- translation: Protocols for interpreting trauma-focused CBT. *Behavioural & Cognitive Psychotherapy*, *35*, 303–316.
- Eap, S., & Hall, G. C. N. (2007). Relevance of RCTs to diverse groups. In A. M. Nezu & C. M. Nezu (Eds.), Evidence-based outcome research: A practical guide to conducting randomized controlled trials for psychosocial interventions. (pp. 425–443). New York: Oxford University Press.
- Garland, A. F., Hurlburt, M. S., & Hawley, K. M. (2006). Examining psychotherapy processes in a services research context. *Clinical Psychology: Science and Practice*, 13, 30–46.
- Garland, A. F., Plemmons, D., & Koontz, L. (2006). Research-practice partnership in mental health: Lessons from participants. Administration and Policy in Mental Health and Mental Health Services Research, 33, 517–528.
- Givens, J. L., Houston, T. K., Van Voorhees, B. W., Ford, D. E., & Cooper, L. A. (2007). Ethnicity and preference for depression treatment. *General Hospital Psychiatry*, 29, 182–191.
- Gone, J. P., & Alcántara, C. (2007). Identifying effective mental health interventions for American Indians and Alaskan Natives: A review of the literature. *Cultural Diversity & Ethnic Minority Psychology*, 13, 356–363.
- Griner, D., & Smith, T. B. (2006). Culturally adapted mental health interventions: A meta analytic review. *Psychotherapy: Theory, Re*search, Practice, Training, 43, 531–548.
- Hall, G. C. N. (2001). Psychotherapy research with ethnic minorities: Empirical, ethical, and conceptual issues. *Journal of Consulting and Clinical Psychology*, 69, 502–510.
- Hinton, D. E., Chhean, D., Pich, V., Saffron, S. A., Hofmann, S. G., & Pollack, M. H. (2005). A randomized controlled trial of cognitivebehavior therapy for Cambodian refugees with treatment-resistant PTSD and panic attacks: A cross-over design. *Journal of Traumatic Stress*, 18, 617–629.
- Hinton, D. E., & Otto, M. W. (2006). Symptom presentation and symptom meaning among traumatized Cambodian refugees: Relevance to a somatically focused cognitive-behavioral therapy. *Cognitive and Behav*ioral Practice. 13, 249–260.
- Hohmann, A. A., & Parron, D. L. (1996). How the new NIH guidelines on inclusion of women and minorities apply: Efficacy trials, effectiveness trials, and validity. *Journal of Consulting and Clinical Psychology*, 64, 851–855.
- Hohmann, A. A., & Shear, M. K. (2002). Community-based intervention research: Coping with the "noise" of real life in study design. *American Journal of Psychiatry*, 159, 201–207.
- Huang, F. Y., Chung, H., Kroenke, K., & Spitzer, R. L. (2006). Racial and ethnic differences in the relationship between depression severity and functional status. *Psychiatric Services*, 57, 498–503.
- Huey, S. J., & Pan, D. (2006). Culture-responsive one-session treatment for phobic Asian Americans: A pilot study. *Psychotherapy: Theory, Re*search and Practice, 43, 549–554.
- Huey, S. J., & Polo, A. J. (2008). Evidence-based psychosocial treatments for ethnic minority youth: Review and meta-analysis. *Journal of Clinical Child and Adolescent Psychology*, 37, 262–301.
- Israel, B. A., Eng, E., Schultz, A. J., Parker, E. A., & Satcher, D. (Eds.). (2005). Methods in community-based participatory research for health. San Francisco: Wiley.
- Ito, K. L., & Maramba, G. G. (2002). Therapeutic beliefs of Asian American therapists: Views from an ethnic-specific clinic. *Transcultural Psychiatry*, 39, 33–73.
- Kataoka, S. H., Stein, B. D., Jaycox, L. H., Wong, M., Escudero, P., Tu, W., & Fink, A. (2003). A school-based mental health program for traumatized Latino immigrant children. *Journal of the American Academy of Child & Adolescent Psychiatry*, 42, 311–318.
- Knight, G. P., & Hill, N. E. (1998). Measurement equivalence in research involving minority adolescents. In: McLoyd, V. & Steinberg, L., (Eds.),

- Study of minority adolescents: Conceptual, methodological and theoretical issues. Hillsdale, NJ: Erlbaum. pp. 183–210.
- Kraemer, H. C., Frank, E., & Kupfer, D. J. (2006). Moderators of treatment outcomes: Clinical, research and policy importance. *Journal of the American Medical Association*, 296, 1286–1289.
- La Roche, M. J., D'Angelo, E., Gualdron, L., & Leavell, J. (2006).
  Culturally sensitive guided imagery for allocentric Latinos: A pilot study. *Psychotherapy: Theory, Research and Practice*, 43, 555–560.
- Le Meyer, O., Zane, N., Cho, Y. I., & Takeuchi, D. T. (2009). Use of specialty mental health services by Asian Americans with psychiatric disorders. *Journal of Consulting and Clinical Psychology*, 77, 1000– 1005
- Mak, W. W. S., Law, R. W., Alvidrez, J., & Pérez-Stable, E. J. (2007).
  Gender and ethnic diversity in NIMH-funded clinical trials: Review of a decade of published research. Administration and Policy in Mental Health and Mental Health Services Research, 34, 497–503.
- Malgady, R. G., & Constantino, G. (1998). Symptom severity in bilingual Hispanics as a function of clinician ethnicity and language of interview. *Psychological Assessment*, 10, 120–127.
- Martinez, C. R., & Eddy, J. M. (2005). Effects of culturally adapted parent management training in Latino youth behavioral health outcomes. *Jour*nal of Consulting and Clinical Psychology, 73, 841–851.
- Matías-Carrelo, L. E., Chávez, L. M., Negrón, G., Canino, G., Aguilar-Gaxiola, S., & Hoppe, S. (2003). The Spanish translation and cultural adaptation of five mental health outcome measures. *Culture, Medicine and Psychiatry*, 27, 291–313.
- McCabe, K. M., & Yeh, M. (2009). The effectiveness of a culturally modified version of Parent Child Interaction Therapy for Mexican American preschoolers with conduct problems. *Journal of Clinical Child and Adolescent Psychology*, 38, 753–759.
- Mendenhall, M. (2008). Factoring culture into outcomes measurement in mental health. In S. Loue & M. Sajatovic (Eds.), *Diversity issues in the* diagnosis, treatment and research of mood disorders (pp. 196–214). New York: Oxford University Press.
- Miller, G. A., & Chapman, J. P. (2001). Misunderstanding of analysis of covariance. *Journal of Abnormal Psychology*, 110, 40–48.
- Miranda, J., Chung, J. Y., Green, B. L., Krupnick, J., Siddique, J., Revicki, D. A., & Belin, T. (2003). Treating depression in predominantly low-income young minority women: A randomized controlled trial. *Journal of the American Medical Association*, 290, 57–65.
- Miranda, J., Nakamura, R., & Bernal, G. (2003). Including ethnic minorities in mental health intervention research: A practical approach to a long-standing problem. *Culture, Medicine, & Psychiatry*, 27, 467–486.
- Okazaki, S., & Tanaka-Matsumi, J. (2006). Cognitive-behavioral assessment with multicultural populations. In P. A. Hays & G. Y. Iwamasa (Eds.), *Cognitive behavioral therapy with culturally diverse populations* (pp. 247–266). Washington, DC: APA.
- Reeves, T. J., & Bennett, C. E. (2004). We the people: Asians in the United States, Census 2000 special reports, CENSR-17. Washington, DC: U.S. Census Bureau.
- Strupp, H. H., & Anderson, T. (1997). On the limitations of therapy manuals. Clinical Psychology: Science and Practice, 4, 76–82.
- Suarez-Morales, L., Matthews, J., Martino, S., Ball, S. A., Rosa, C., Farentinos, C., ... Carroll, K. M. (2007). Issues in designing and implementing a Spanish-language multi-site clinical trial. *American Journal on Addictions*, 16, 206–215.
- Thomas, S. B., & Quinn, S. C. (1991). The Tuskegee syphilis study, 1932 to 1972: Implications for HIV education and AIDS risk education programs in the Black community. *American Journal of Public Health*, 81, 1498–1504.

- U.S. Department of Health and Human Services. (2001). *Mental health:* Culture, race and ethnicity A suppl. to Mental health: A report of the Surgeon General. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services.
- Wallerstein, N. B., & Duran, B. (2006). Using community-based participatory research to address health disparities. *Health Promotions Practice*, 7, 312–323.
- Weisz, J. R., Donenberg, G. R., Han, S. S., & Weiss, B. (1995). Bridging
- the gap between laboratory and clinic in child and adolescent psychotherapy. *Journal of Consulting and Clinical Psychology*, 63, 688-701.
- Wells, K., Miranda, J., Bruce, M. L., Alegria, M., & Wallerstein, N. (2004). Bridging community intervention and mental health services research. *American Journal of Psychiatry*, 161, 855–963.
- Yali, A. M., & Revenson, T. A. (2004). How changes in population demographics will impact health psychology: Incorporating a broader notion of cultural competence into the field. *Health Psychology*, 23, 147–155.

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